IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS AG, NOVARTIS PHARMACEUTICALS CORPORATION, MITSUBISHI TANABE PHARMA CORPORATION, and MITSUI SUGAR CO., LTD. Plaintiffs, v. EZRA VENTURES , LLC, Defendants.	C.A. No. 15-0150-LPS

PLAINTIFFS' BRIEF IN OPPOSITION TO
EZRA'S MOTION FOR JUDGMENT ON THE PLEADINGS UNDER FRCP 12(C)

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PRELIMINARY STATEMENT

Ezra seeks to disrupt a balance Congress struck between encouraging future investment in new medicines and streamlining access to generic drugs. Congress enacted the Hatch-Waxman Act, an integrated set of laws framing this balance. The laws reduced the efforts needed by generic drug makers to achieve FDA approval of a copy of an already-approved medicine. They also addressed an unfairness regarding innovator patent rights. A drug innovator will often wait years for FDA approval to sell a new medicine due to necessary, but lengthy, clinical trials and FDA review of its new medicine. Only when the new medicine is deemed safe and effective by the FDA will the innovator be permitted to sell it. Meanwhile, the innovator's patent rights specific to that new medicine cannot be used. Part of the Hatch-Waxman framework is 35 U.S.C § 156, allowing the patent-holder to restore up to five years of patent life to compensate for this delay.

Ezra's motion seeks to deprive the patent-holder of the full rights Congress granted in Section 156. In particular, Ezra attacks the restored term of the patent at issue in this case, U.S. Patent No. 5,604,229, which covers Plaintiffs' multiple sclerosis drug, Gilenya®. Ezra says that the '229 patent's term should not have been extended further than the term of a different patent that covers Gilenya®, U.S. Patent No. 6,004,565. Section 156, however, plainly allows patent-holders to choose any patent covering its new drug for patent term restoration, a key right of the statutory framework. The statute nowhere limits the extension to the shorter-duration patent. Indeed, the legislative history of the statute addressed this exact issue. None of Ezra's arguments to the contrary has any merit.

First, Ezra admits Section 156 allows a patent-holder to identify which of several patents should be restored, but criticizes Plaintiffs for making the "wrong" choice. Ezra's position is in

conflict with the language of the statute and its underlying Congressional Record. In fact, Congress debated the exact issue of choice and decided to give the patent-holder "the flexibility to select the most important patent for extension." (Jane M. Love, Ph.D. Declaration (Love Decl.) Ex. A.[1] 130 Cong. Rec. H9130, at 9132 (Sept. 6, 1984)). Congress knew how to restrict patent-holders' rights if needed, such as, by capping any restoration at five years, or by limiting the scope of the restored claims. Both restrictions are explicit in the statute. In contrast, the statute empowered the patent owner to choose the patent for restoration, just as Congress intended. Plaintiffs here chose the '229 patent. The Patent Office and FDA approved the extension of the '229 patent term. Ezra makes no showing whatsoever that a single statutory step, procedure or filing was in error. Second-guessing the statutory right of the patent-holder to choose which patent to restore is no basis for a motion for judgment on the pleadings.

Second, Ezra mines century-old and off-topic cases to prop up a so-called "fundamental principle" in efforts to justify its novel attack. According to Ezra, the public has an automatic right to practice an expired patent, rendering the patent restoration unjustified. As the Congressional Record shows, public interest was taken into account and Ezra cites no violation of that framework. Ezra presents an incomplete picture. Expiry of a patent gives the public freedom from the exclusive right of that particular patent. However, other overlapping patents, may and often do exist. These are missing from the picture Ezra presents.

Third, Ezra makes the wholly unprecedented argument that double patenting prohibits a patent-holder from choosing a patent that would otherwise be eligible under Section 156. This law authorizes adding back a limited patent term, upon application. A key premise of this law is that a patent-holder chooses a single patent to be restored from a stable of other patents that will

[1] Exhibits to the Love Decl. will be labeled "Ex. __."

not be restored, all of which cover the new medicine. Double patenting rules cannot and do not apply here. Moreover, double patenting is a fact-focused analysis—inappropriate under Federal Rule of Civil Procedure 12(c). Deep analysis of the patents, the claims, their file histories, and extrinsic evidence—including expert testimony—is required. None of that work was done by Ezra, nor can it be.

Ezra chooses to ignore this Court's specific discouragement of Rule 12(c) motions even though the other Defendants in the Related Fingolimod Cases refused to join this motion. Ezra's motion is meritless and should be denied.

STATEMENT OF FACTS

I. Patent Term Restoration Under 35 U.S.C. § 156

The Hatch-Waxman Act was designed to benefit both makers of generic drugs and research-based pharmaceutical companies. *See* The Drug Price Competition and Patent Term Restoration Act of 1984, Pub.L. 98-417, 98 Stat. 1585. Congress endeavored to balance two competing policy objectives: incentivize innovator pharmaceutical companies to make investments in developing new medicines and enable a more streamlined approval process for generic drugs. (Ex. B. H.R.Rep. No. 98-857, pt. 1 at 14 (1984) reprinted in 1984 U.S.C.C.A.N. 2647, 2647 and H.R.Rep. No. 98-857, pt. 1 at 15, 1984 U.S.C.C.A.N. 2647, 2648.)

In the Congressional Record, Congressman Waxman deliberated on replacing language in the bill that would have, as a rule, forced the patent-holder to restore the first-issued patent only. He considered instead a rule allowing the patent-holder to choose which patent to extend. He recognized that this change "gives the patent-holder the flexibility to select the most important patent for extension" and that the new rule did not undercut the one-patent restriction. (Ex. A. 130 Cong. Rec. H9130, at 9132 (Sept. 6, 1984)). Accordingly, in order "to obtain an

extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Director" of the Patent Office. "[T]he application shall contain…the identity of the patent for which extension is being sought…." 35 U.S.C. §156(d)(1). Lawmakers knew multiple patents could and would cover a new drug product. Evidence of that is that the Act required a public listing of all patents that the innovator believed to cover the new drug product, a.k.a. the Orange Book. 21 U.S.C. § 355(b)(1), (j)(7).

On November 2015, President Obama ratified a new law amending Section 156 (Pub. L. 114-89). Drug products containing controlled substances even if approved by FDA, may not be marketed until the Drug Enforcement Agency ("DEA") determines the "scheduling" of the controlled substance under the Controlled Substances Act ("CSA"). The amendment makes the date of approval for a controlled substance to be the latest approval date from FDA or DEA. This ensures the patent-holder will not be disadvantaged by a CSA scheduling delay. Congressional and Executive intent behind Section 156 could not be more clear that the extension provided under Section 156 can reach far past other, related patents.

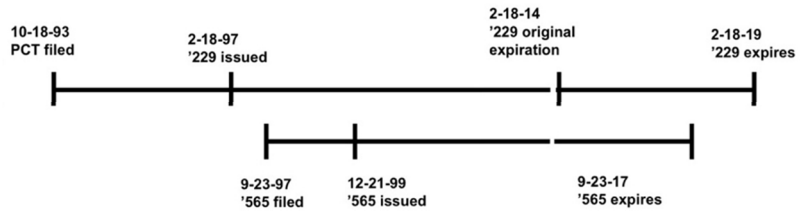
II. The '229 Patent and File History

The '229 patent arose from an application filed in 1992 and was granted in 1997. The application named six inventors and disclosed over 400 examples of chemical compounds useful as immunosuppressants. The patent's natural expiration date would have been in 2014, but prior to expiration. Plaintiffs filed an application for patent term restoration in 2010. The Patent Office issued a certificate granting a restoration of five years, resulting in a new expiration date of February 18, 2019. The Patent Office and FDA reviewed and approved the application. *See* (Ex. C. File history of the '229 patent: Notice of Final Determination for Eligibility (October 20,

2013) and Ex. D. File history of the '229 patent: FDA Final Eligibility Letter (December 18, 2012)). The '229 patent was listed in the Orange Book. (D.I. 71, Ezra's Ex. B.)

III. The '565 Patent and File History

The patent application giving rise to the '565 patent was filed on September 23, 1997, seven months after the issuance of the '229 patent. See timeline below.



The '565 patent names two inventors, Drs. Chiba and Adachi. Both were also inventors on the '229 patent. The invention of the '565 patent involves a newly discovered immunosuppression mechanism. The '565 specification identified the '229 patent as disclosing compounds useful in the new invention. ('565 Patent, 4:41-49.). An Information Disclosure Statement listing the '229 patent was submitted to the PTO. (*See* Ex. E. File history of the '565 patent: IDS filed on February 10, 1998.) The '229 patent formed the basis of several initial patentability rejections of claims, which were ultimately overcome by the applicants. (*See* Ex. E. File history of the '565 patent: Non-final office action on June 8, 1998.) The Patent Examiner rejected the pending claims for double patenting, both under 35 U.S.C. § 101 and under the doctrine of obviousness-type double patenting based on the '229 patent. The rejections were overcome. No terminal disclaimer was required. The '565 patent issued on December 21, 1999. It was timely listed in the Orange Book.

IV. Gilenya® and FDA Regulatory Approval

Gilenya® is the first approved oral medicine to treat multiple sclerosis. The active ingredient is fingolimod, which established a new class of compounds useful to treat multiple sclerosis. (Ex. F. Gilenya® Drug Label.) On December 18, 2009, a New Drug Application for Gilenya® was filed with FDA. (Ex. G. NDA Approval Letter for Gilenya®.) The FDA issued a press release on September 22, 2010, announcing approval of Gilenya® capsules, stating "Gilenya® is the first oral drug that can slow the progression of disability and reduce the frequency and the symptoms of MS, offering patients an alternative to currently available injectable therapies." The FDA press release said "Gilenya® is the first in a new class of drugs that block some blood cells in lymph nodes, reducing their migration in the brain and spinal cord, which may help with reducing the severity of MS." (Ex. H. FDA Press Release Dated September 22, 2010.)

ARGUMENT

I. The Plain Language of Section 156 Defeats Ezra's Motion

Ezra argues that by restoring the '229 patent term, patentees "effectively" extended the term of the '565 patent and thus violate Section 156's requirement that only one patent may be extended. Ezra cites no authority to support its position. Instead, Ezra retreats to policy arguments related to the public's freedom to practice the subject matter of expired patents. The statute simply trumps these ideas. Ezra's allegations taken to their end would defeat the purpose of 35 U.S.C. § 156 and confound the purpose of the patent law to encourage innovation.

A. Congress Granted Patent-Holders a Choice Among Related Patents

Congress recognized that pharmaceutical patent holders often have more than one patent covering a drug product. The legislative history shows the debate between a rule instructing

patent-holders to extend only the first-issued patent and a rule allowing the patent-holders to choose for themselves which patent to extend. Choice won out. The lengthy statute reflects this decision in a few ways. The recognition by Congress that there may be more than one patent that could be eligible for extension is evident in Section 156(c)(4): "in no event shall more than one patent be extended under subsection (e)(1) for the same regulatory review period for any product." Thus, the patent term restoration opportunity was limited to one patent per regulatory review period. *See* 35 U.S.C. § 156(c)(4)(2012). Then, the statute tells the patent-holder "to obtain an extension of the term of a patent…the owner of record of the patent or its agent shall submit an application to the Director." And, "the application shall contain…the identity of the patent for which an extension is being sought…" *See* 35 U.S.C. § 156(d)(1). The law expressly gives the patent-holder the power to choose which patent to restore.

Ezra also ignores the statutory restriction on the *scope* of the exclusionary right under Section 156—more balancing of interests within the Hatch-Waxman Act. Although the patent-holder gets an extended term, the scope of the patent right is narrowly tailored to only cover what was reviewed and approved by FDA. The right is limited "to any use approved for the product…." *See* 35 U.S.C. § 156(b)(1) and (2). If the patent claims other things in addition to the approved product, the rights covering the other things expire with the original expiration date of the patent. 35 U.S.C. § 156(b)(1). In this case, patent claims that do not cover Gilenya® in the '229 patent will not be in force during the extended term. Even if the patent claims encompass more than Gilenya®, they will only be enforceable against the approved product. 35 U.S.C. § 156(b)(1). Ezra is silent on this nuance of the balanced laws.

Ezra complains the patent-holders here made the "wrong choice." But, Congress wanted the patent-holder to be able to choose for themselves which patent term to restore. Congressman

Waxman wanted to give "the patent-holder the flexibility to select the most important patent for extension." (*See* Ex. A. 130 Cong. Rec. H9130, at 9132 (Sept. 6, 1984)). The Federal Circuit has since confirmed that Section 156 allows for patent holders to choose from among multiple patents on the same product. For instance, in a case featured in Ezra's brief, a patent subject to a terminal disclaimer was ruled to be a proper choice for restoration. The court said that "Congress chose not to limit the availability of a PTE to a specific parent or continuation patent but instead chose a flexible approach which gave the patentee the choice. We see no reason why a patentee should not have the same choice between an earlier patent and a later patent related by a terminal disclaimer." *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1323 (Fed. Cir. 2007).

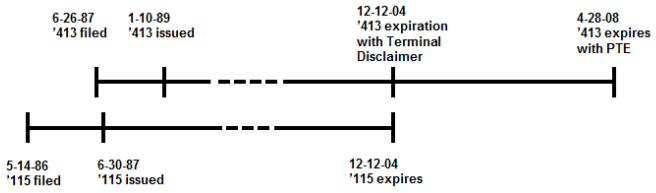
Even today, Congressional intent is clear. In November of 2015, the President ratified an amendment of Section 156, permitting the restoration period for patents covering controlled substances to begin only after the later of FDA or DEA approval. Ezra is wrong in its attempt to take back the power of choice that Congress granted.

B. Ezra Attempts to Artificially Narrow the *Merck* Holding

Ezra does not dispute *Merck's* holding, but tries to limit the case to its facts. *Merck* cannot be so limited—it merely confirmed what is apparent from the face of the statute itself. Patent owners may choose whatever patent they want to restore under Section 156. The *Merck* facts are even more extreme than the present case, because unlike here, the patent in *Merck* had a terminal disclaimer. Terminal disclaimers are often used to overcome double patenting rejections. They set the patent expiration dates to the earliest expiration between the two patents. However, this only emphasizes that Section 156 applies where there are two patents deemed to be so overlapping in subject matter as to require a terminal disclaimer. *Merck* is a vivid example

of how a restored patent can properly go beyond the expiration date of another overlapping patent.

In *Merck*, the '413 patent had a terminal disclaimer over the '115 patent. *Merck & Co.*, 482 F.3d at 1319. The '115 patent expired December 2004. *Id.* However, the '413 patent received a patent term restoration and instead of expiring in December 2004, it was enforceable until April 2008. *Id.* The extra term was computed from the expiration date resulting from the terminal disclaimer, thus, the restored patent was to remain enforceable for a time after the expiration of the related patent. *Id.* at 1323. That is exactly the situation here—the '229 patent will remain in force after the expiration of the '565 patent.



Ezra tries to narrow *Merck* to only where (1) patents are related and a terminal disclaimer is required and (2) patentees did not have a choice (as Plaintiffs allegedly do here) to select a patent which would not have "an effective extension on the two unrelated patents." (D.I. 71, at 9.) These "distinctions" are illusory. The *Merck* court uses no language limiting its ruling in these ways. Nor does Ezra's second so-called distinction make any sense—nothing in *Merck* suggests those patent owners had no choice. A patent with a terminal disclaimer which is extended under Section 156 *necessarily* extends beyond the patent over which it was terminally disclaimed. In other words, the patent extended under Section 156 would always have a later expiration date than the double-patenting reference.

Others have not viewed the *Merck* case as so limited: the PTO's Manual for Patent Examining Procedures ("MPEP") cites *Merck*, making the eligibility of terminally disclaimed patents for 35 U.S.C. § 156 extensions explicit. *See* MPEP § 2751. Also weighing against Ezra's position is 37 C.F.R. § 1.775, a PTO regulation saying the patent term extension due to regulatory delay runs from the "original expiration date of the patent or any earlier date set by a terminal disclaimer," echoing *Merck*'s holding.

C. Ezra's Choice Would Result in Three More Years of Patent Term

Ironically, Ezra's choice of the '565 patent for extension would lead to three additional years of patent coverage. Ezra agrees Plaintiffs had a choice, but then maintains "plaintiffs could have avoided this situation" (of "effectively acquir[ing] a PTE for both the '229 and the '565 patents") by choosing to extend the '565 patent instead. If the same five years of patent term were applied to the '565 patent, it would not expire until 2022. Ezra's choice would have kept the public subject to an exclusionary right for three additional years past the 2019 expiration date of the '229 patent.

II. Ezra's Policy Arguments Lack Merit

Ezra bases its next argument on a so-called "fundamental principle" that the subject matter of an expired patent "is dedicated to the public, free for anyone to make, use or sell," citing five cases (four of which are more than 50 years old). Ezra cites only dicta and its appeal to this supposed policy is unavailing. After a robust public commentary period, Congress necessarily balanced the various competing interests when it passed Section 156 in concert with other laws to properly calibrate all interests. Ezra cannot resort to vague policy concerns now to effectively overturn this balance Congress struck. When interpreting a statute, courts look first to its language. An additional tool of analysis is legislative history. But, if the plain language of

the statute is unambiguous, then only an extraordinary showing of contrary intentions would justify a limitation on the plain meaning of the statutory language. "When we find the terms of a statute unambiguous, judicial inquiry is complete, except in rare and exceptional circumstances." *Garcia v. United States*, 469 U.S. 70, 75 (1984). Ezra makes no showing on any supposed ambiguity in the statute.

In any event, the "fundamental principle" Ezra cites is not real, and is cobbled together only from dicta in inapposite cases. *Singer*, decided more than a century ago in 1896, is a trademark infringement case, and not applicable here. *Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169 (1896). The public's right to use the name "Singer" after expiration of a patent in 1896 is not applicable to the present case. *Kellogg* (1938) concerns unfair use of the trade name "shredded wheat," and not relevant here. *Kellogg Co. v. Nat'l Biscuit Co.*, 305 U.S. 111 (1938). *Scott Paper* (1945) is a patent case, but the holding addresses the question of whether the assignor of a patent is estopped from defending an infringement suit, an issue not relevant here. *Scott Paper Co. v. Marcalus Mfg. Co.*, 326 U.S. 249 (1945). *Sears* (1964) is about whether unfair competition law can impose liability for a product not protected by a patent, and not relevant here. *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 230 (1964). A fifth case is from 2015 but still misses the mark: *Kimble v. Marvel Entertainment LLC* finds a patent-holder cannot charge royalties for the use of his invention after its patent term expired, exploring the *Brulotte* line of cases; also not relevant. Ezra cites not one case related to Section 156 to support its theory. 135 S. Ct. 2401 (2015) (citing *Brulotte v. Thys Co.*, 379 U.S. 29 (1964)).

In sum, Ezra appears to have misunderstood what a patent right is. A patent confers a right of exclusion, not permission. *Biotechnology Indus. Org. v. D.C.*, 505 F.3d 1343, 1346 (Fed. Cir. 2007). ("It is, of course, well-established that the patent laws, including the Drug

Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), Pub.L. No. 98-417, 98 Stat. 1585 (codified as amended at 35 U.S.C. § 156), do not 'create any affirmative right to make, use, or sell anything.'") (quoting *Leatherman Tool Group v. Cooper Indus.,* 131 F.3d 1011, 1015 (Fed. Cir. 1997)). But the right that the patent laws do confer upon patent holders—the right to "exclude others from making, using, or selling a claimed invention for a limited period of time"—is not granted in a vacuum or for its own sake." *Id.* at 1346. When a patent expires, the public is still subject to the exclusionary rights of other patent holders and is not free to practice any method of any expired patent. *Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Trust*, 764 F.3d. 1366, 1379 (Fed. Cir. 2014).) Therefore, the expiration of the '565 patent is yet another example of a patent claim expiring while another, overlapping patent claim continues in force.

As an aside, Ezra flails about suggesting to the court various changes to the patent law including implied licenses, adjusted patent terms, and a divvying up of the patent rights by uses. (D.I. 71, at 11.) None of these ideas is supported by any precedent, or even reasoning, and should be dismissed out of hand.

III. A Double Patenting Analysis is Inapposite Under 35 U.S.C. § 156

A. Section 101 Double Patenting Does Not Apply

Statutory double patenting under 35 U.S.C. § 101 prohibits the identical invention from being claimed twice in two different patents. A test for "same invention" is whether one of the claims could be literally infringed without literally infringing the other. If it could be then the claims do not define identically the same invention. *In re Vogel*, 422 F.2d 438, 441 (CCPA 1970) (35 U.S.C. § 101 prevents two patents from issuing on the same invention meaning identical subject matter); *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d

1272, 1277–78 (Fed. Cir. 1992); *Research Corp. Techs., Inc. v. Gensia Labs., Inc.*, 10 Fed. Appx. 856, 863 (Fed. Cir. 2001).

Section 101 double patenting does not apply to this case because the claims of the '229 patent and the '565 patent are different. The words of the claims do not define the same identical invention. In fact, Ezra admits that Plaintiffs have "two unrelated patents" in a different section of their brief. (D.I. 71, at 6.) Here, Ezra conveniently changes its position to argue that the inventions are the same.

B. Obviousness-Type Double Patenting Does Not Apply to Patent Restoration

Ezra argues the '229 patent is invalid due to double patenting over the '565 patent. Section 156 precludes this theory. Ezra cites no case for the proposition that either the obviousness-type double patenting doctrine or statutory double patenting can invalidate the restored term of a patent under Section 156. The lawmakers were aware that patent holders would likely have multiple patents, each covering an aspect of a drug product. In fact, another part of the Hatch-Waxman laws requires such patents to be listed publicly. 21 U.S.C. § 355(b)(1), (j)(7). Thus, the lawmakers were aware of the multiple-patent issue and proceeded to pass Section 156 into law. Ezra cites no authority saying otherwise.

Double patenting doctrine is intended to address unjustified extensions of patent terms. "The fundamental reason for the rule [of obviousness-type double patenting] is to prevent unjustified time-wise extension of the right to exclude granted by a patent no matter how the extension is brought about." *In re Van Ornum*, 686 F.2d 937, 943–44 (CCPA 1982) (*quoting In re Schneller,* 55 C.C.P.A. 1375, 397 F.2d 350, 354 (1968)). Here, the restoration of a patent term by exercising a statutory right is justifiable.

C. An Obviousness-Type Double Patenting Analysis Requires a Factual Record

An obviousness-type double patenting analysis has two steps. "First, …a court construes the claim in the earlier patent and the claim in the later patent and determines the differences. Second, the court determines whether the differences in the subject matter between the two claims render the claims patentably distinct." *Eli Lilly & Co. v. Barr Labs., Inc.,* 251 F.3d 955, 968 (Fed. Cir. 2001) (internal citation omitted). Thus, "two fact-intensive inquiries are needed: claim construction and patentable distinctness. Construing patent claims, unlike interpreting statutes written for the general public, requires delving into technical facts written for a specialist audience. "[P]atent claims concern a small portion of [the] public" like technical experts and patent administrators that "consider relevant technical facts before the award of a patent." *Teva Pharmaceuticals USA v. Sandoz, Inc.,* 135 S. Ct. 831, 840 (2015).

Ezra offers no factual evidence, nor can it, having chosen to move under Rule 12(c). Recognizing this vacancy, Ezra litters its brief with highly disputable and uncredited assertions. (*See* D.I. 71, at 14-16). Ezra invokes complex scientific facts with no citations, experts, discovery or claim construction. Even the attempt to make a showing is inappropriate here. Ezra cannot remain within the pleadings and at the same time marshal sufficient facts to meet its burden. *See Carman Indus, Inc. v. Wahl*, 724 F.2d 932, 940 (Fed. Cir. 1983); *Symbol Techs, Inc. v. Opticon, Inc*., 935 F.2d 1569, 1580 (Fed. Cir. 1991) ("Double patenting is an affirmative defense. Opticon was therefore required to prove double patenting by clear and convincing evidence, a heavy and unshifting burden.") (internal citation omitted); *Otsuka Pharm. Co. v. Sandoz, Inc.,* 678 F.3d 1280, 1290 (Fed. Cir. 2012 ("[Similar to obviousness], obviousness-type double patenting is a question of law with underlying findings of fact.")).

Finally, Ezra tries to veil the double patenting question as a theoretical one, insisting the motion presents a "purely legal issue." (*See* D.I. 71, at 6). Either way, Ezra commits procedural error. If the question requires a factual record, it is not permitted under FRCP 12(c). If the question is theoretical, it is not proper in this case.

D. *Gilead* Is Limited to Its Facts, Which Are Not Relevant Here

Ezra tries to argue that *Gilead Sciences, Inc. v. NatCo Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014), supports its position. Not true. *Gilead* has nothing to do with Section 156 restorations. In the present action, the '229 patent has a longer term than the '565 patent only by virtue of an extension of term under Section 156. *Gilead*, on the other hand, involved a patent with a longer natural term than the double-patenting reference. This distinction alone renders *Gilead* inapposite.

The holding in *Gilead* is limited to factual circumstances where the patent-owners had allegedly "crafted" a filing strategy which kept the Patent Examiner in the dark about their second patent application. "We therefore hold that an earlier-expiring patent can qualify as an obviousness-type double patenting reference for a later-expiring patent *under the circumstances here*." *Id.* at 1217, (emphasis added). "We conclude *under the circumstances of this case* that it can and, therefore, that the district court erred…." *Id.* at 1212 (emphasis added). The *Gilead* court focuses on the curious fact that two patents were filed with the same inventors, and largely overlapping specifications, but did not claim priority to the same parent, or even disclose the existence of the other to the PTO. *See generally id.*

There was no such "crafting" in the present case. The two patents here have different inventive entities. The specifications do not overlap. The '229 patent discloses over 400 compound examples over 147 pages. The '565 patent is only 30 pages long, focused on

lymphocyte homing and immunosuppression. The patents are unrelated, as Ezra admits. The '565 patent does not claim priority to the '229 patent. And unlike *Gilead*, where each of the two patents was silent about the other, the '229 patent was disclosed to the Patent Office in multiple ways during examination of the '565 patent. The '229 patent was cited in the '565 patent specification as disclosing compounds useful in the claimed methods. (*See* D.I. 71, Ezra's Ex. B. '565 Patent, 4:41-49.)

The '229 patent was listed in an Information Disclosure Statement. (*See* Ex. E. File history of the '565 patent: IDS filed on February 10, 1998.) And, the '229 patent was one of the references cited by the Patent Examiner himself in making claim rejections during examination of the '565 patent. (*See* Ex. E. File history of the '565 patent: Non-final office action on June 8, 1998.) The '565 patent was not disclosed in the '229 patent file history because it didn't exist at the time the '229 patent was under examination. *Gilead* is inapposite.

IV. This Rule 12(c) Motion Is Procedurally Improper

The affirmative defenses of double patenting and invalid patent term extension typically require the evaluation of a host of factors and information that are outside the pleadings and the proper consideration of a Rule 12(c) motion. *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Trust*, 764 F.3d 1366, 1377 (Fed. Cir. 2014) (considering inventors' trial testimony in its discussion of double patenting). These factors often include: expert testimony clarifying the scope of the patents in question; inventor testimony to determine, among other things, whether there was any gamesmanship on the part of the inventors or their assignees during the prosecution of the patents; the file histories of the patents in suit or patents in question; and claim construction. *See id.* Here, the record relating to all of these factors is underdeveloped and will likely remain so through expert discovery. Indeed, the Court typically

does not hear dispositive motions in ANDA cases, in which the Court is the finder of fact. (*See* D.I. 41, Scheduling Order, at ¶ 20 ("Absent agreement between the parties, the Court will generally not hear case dispositive motions in ANDA cases.")).

Ezra's Rule 12(c) motion calls for the Court to compare the scope of '229 patent and the scope of the '565 patent without the requisite information. This would, in effect, punish Plaintiffs for not having included such information in the complaint in the first instance. But "a plaintiff is not required to plead, in a complaint, facts sufficient to overcome an affirmative defense." *Schmidt v. Skolas*, 770 F.3d 241, 251 (3d Cir. 2014).

Ezra's motion would also likely force the court to improperly engage in claim construction without the procedural protections of a *Markman* hearing. *Novartis Pharms. Corp. v. Actavis*, *Inc.*, No. 12–366-RGA-CJB, 2012 WL LEXIS 6212619, at *7 (D. Del. Dec. 5, 2012) ("[C]ourts have reasoned that it is unsuitable to engage in such an inquiry at the pleading stage, because claim construction can be illuminated by the consideration of extrinsic evidence—evidence that is often not before the court at that stage."), adopted No. 12-366-RGA-CJB (Dec. 28, 2012); s*ee also id.* ("[Courts] also note that a claim construction analysis at the pleading stage does not benefit from the procedures (including an exchange of discovery documents relating to infringement, the exchange of proposed constructions and extensive briefing) that typically precede a Markman hearing."). Ezra's 12(c) motion would necessitate the construction of claim terms of the '565 patent as well, which is not contemplated in this case.

In any event, even if the requisite information were currently available to the Court—which it is not—such information is outside of the pleadings, and therefore, deciding this motion pursuant to Rule 12(c) would be inappropriate. While it is an open question as to whether the

file history of the '229 patent can be considered in a Rule 12(c) motion,[2] the file history of the '565 patent—which is not asserted in this suit—as well as the inventor and expert testimony needed to decide this motion, are not properly considered as part of a Rule 12(c) motion. *Novartis Pharms. Corp.*, 2012 WL LEXIS 6212619, at *2 ("In deciding whether judgment on the pleadings is appropriate, courts may consider the pleadings, corresponding exhibits thereto, and documents incorporated by reference.")

Thus, Plaintiffs respectfully submit that this Court should convert Ezra's Rule 12(c) motion to a motion for summary judgment and then deny that motion for lack of discovery under Rule 56(d). *Rose v. Bartle*, 871 F.2d 331, 340 (3d Cir. Pa. 1989); Fed. R. Civ. P. 12(d); Fed. R. Civ. P 56(d).

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court deny Ezra's motion for judgment on the pleadings under Fed. R. Civ. P. 12(c).

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[2] *See Hickory Springs Mfg. Co. v. R&D Plastics of Hickory, Ltd.*, No. 5:14CV00093, 2015 U.S. Dist. LEXIS 94079, at *10 (W.D.N.C. July 20, 2015) (converting Rule 12(b)(6) motion into one for summary judgment because file history not part of pleadings). *But see In re Bendamustine Consol. Cases*, No. 13-2046, 2015 U.S. Dist. LEXIS 55963, at *8-9 (D. Del. Apr. 29, 2015) ("[W]hat is critical is whether the claims in the complaint are 'based' on an extrinsic document and not merely whether the extrinsic document was explicitly cited. The court is satisfied that the '190 and '863 patents, their file histories, as well as the Moving Defendants' ANDA filings are all properly before the court, even at this preliminary stage.") (internal citations and quotation marks omitted).

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